Initial Experience Using the Gore Embolic Filter in Carotid Interventions

Marius Hornung, MD[1]; Jennifer Franke, MD[1]; Stefan C. Bertog, MD[1]; Sameer Gafoor, MD[1]; Iris Grunwald, MD[1,2]; Horst Sievert, MD[1,2]

ABSTRACT: Background. This is the first clinical report on experience in the use of the Gore embolic filter in carotid interventions. It was designed as a guidewire and embolic protection system in carotid, peripheral, and coronary interventions. The ability to capture debris is driven by the frame of the filter, which is designed to improve vessel wall apposition and allows a short landing zone. **Methods.** We report the results of the first 20 consecutive patients undergoing carotid artery stenting using the Gore embolic filter in our institution. We analyzed technical success as well as the occurrence of transient ischemic attack (TIA), stroke, or death periprocedurally and through 30 days of follow-up. Mean patient age was 72 years and 12 patients (60%) were male. Seven patients were symptomatic and 4 patients suffered recurrent neurological events. **Results.** Technical success was achieved in all procedures. In 1 patient, the retrieval catheter was caught between the proximal struts of the stent and required further retrieval maneuvers. Within 30 days of follow-up, 1 patient had a TIA. No stroke, death, or myocardial infarction occurred. **Conclusion.** This initial experience suggests that the Gore embolic filter device can be used safely for distal embolic protection during carotid stenting procedures with high technical success.

J INVASIVE CARDIOL 2016;28(8):xxx-xxx
KEY WORDS: embolic protection, TIA, peripheral vascular disease, stroke

Over the last two decades, carotid artery stenting (CAS) has established itself as an alternative to carotid endarterectomy (CEA) in the treatment of carotid stenoses in patients at high risk for surgery.[1-5] Another step in the improvement of CAS was managed by demonstrating reduced cerebral embolic event rates with the use of cerebral embolic protection systems within large carotid stent registries.[6-8] However, despite the use of distal filter devices, the occurrence of cerebral embolic events could be documented.[9,10] Brain imaging studies and the use of transcranial Doppler investigations could show lower silent cerebral embolic event rates within endarterectomy compared with CAS despite the use of filter devices.[11,12] The occurrence of cerebral embolic events despite the use of distal filter devices may be related to different weaknesses of this type of protection device. A large proportion of emboli is <80 µm in size,[13,14] but the pore size of most available filter devices is >80 µm. Besides, due to the rigidity of many filter devices, and a required minimal distal landing zone depending on the length of the basket of the filter device, the vessel wall apposition (especially in tortuous vessel segments) may not be optimal and could therefore allow cerebral embolization.[15,16] Nevertheless, randomized controlled trials comparing CEA and CAS mandating for embolic protection were able to demonstrate the equivalence of both procedures with regard to the occurrence of stroke.[17,18] These trials were performed using rather old filter devices. The newly designed Gore embolic filter (Gore Medical) incorporates a diamond-shaped frame that optimizes vessel wall apposition and minimizes the required distal landing zone. This might be advantageous in tortuous vessels with small landing zones and severe kinking. Besides, this filter was designed to be used in carotid artery interventions as well as in coronary and peripheral interventions. Herewith, we report the first clinical experiences with the use of the Gore embolic filter in the context of CAS.

Methods

We used the Gore embolic filter for distal embolic protection device in patients undergoing CAS of the proximal internal carotid artery (ICA) or carotid bifurcation with a symptomatic stenosis of ≥50% or asymptomatic stenosis of ≥70% (according to NASCET criteria).[19] *Symptomatic status* was defined as carotid artery stenosis associated with ipsilateral transient ischemic attack (TIA), amaurosis fugax, ischemic stroke, or retinal infarction within 6 months prior to enrollment.

Baseline examinations prior to the procedure consisted of a physical examination as well as documentation of the relevant medical history including cardiovascular risk factors, past cardiovascular and neurological events, current symptoms of concomitant cardiovascular disease, medication, and patient demographic information. Furthermore, we conducted routine laboratory tests (including cardiac enzymes) and a 12-lead electrocardiogram. We performed either color-coded duplex ultrasound, magnetic resonance angiography, or selective angiography for preprocedure assessment of the extracranial vessels.

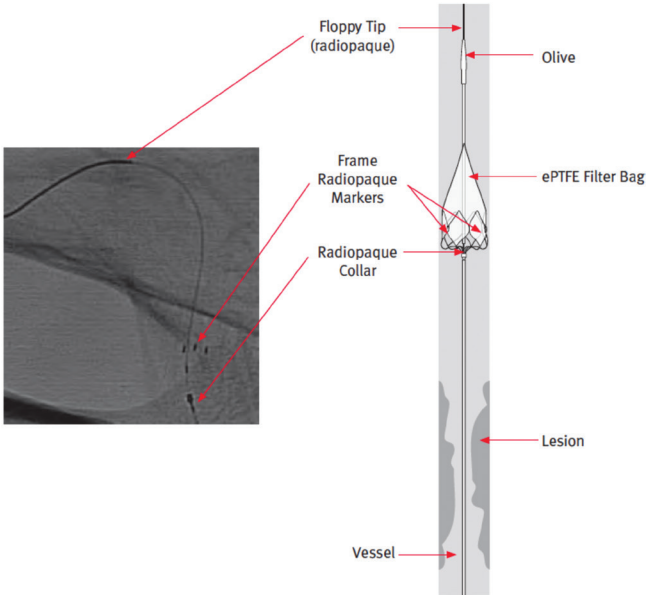

FIGURE 1. Schematic representation of the Gore embolic filter with labeling of the most important components.

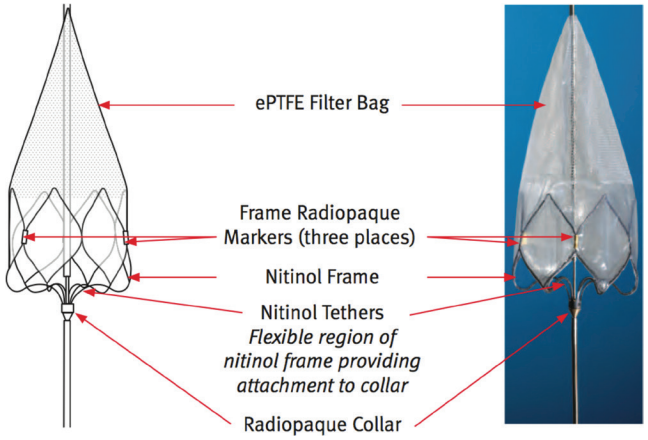

FIGURE 2. Angiographic picture of the deployed Gore embolic filter with labeling of the most important components.

Patients received 100 mg aspirin and 75 mg clopidogrel, starting at least 3 days before the procedure. Alternatively, loading doses of 500 mg aspirin and 300 mg clopidogrel were administered the day before the procedure. At the beginning of the intervention, unfractionated heparin (5000-10,000 IU) was administered to achieve an activated clotting time (ACT) of at least 250 seconds. At 2-3 minutes before stent dilation, 1 mg of atropine was administered to prevent a vasovagal reaction due to stimulation of the baroreceptors in the area of the carotid bulb. Post procedure, all patients were on 100 mg aspirin daily indefinitely and 75 mg clopidogrel daily for a minimum of 30 days.

Prior to the procedure and before discharge, certified physicians carried out a neurological assessment consisting of a complete examination using the NIH (National Institute of Health) stroke scale. In cases of suspected neurological events (TIA, minor or major strokes), cranial imaging was performed and a neurologist was consulted.

The procedures were performed under local anesthesia applied in the area of vascular access. Baseline angiography of the ipsilateral side included at least two projections to determine the grade of stenosis according to the NASCET criteria,[19] and thus, to confirm subject eligibility. Furthermore, we performed an angiography of the ipsilateral intracerebral circulation immediately before and after the carotid intervention. Patient heart rates and blood pressures were monitored continuously throughout the procedure. In addition to continuous heart rate, electrocardiogram, and blood pressure monitoring, periodic neurologic assessments were performed during every critical step of the procedure.

The Gore embolic filter system consists of three parts: the embolic filter device, a delivery catheter, and a retrieval catheter. The filter is available in two sizes: a 5 mm filter diameter for a reference vessel diameter from 2.5-4.0 mm, and a 7 mm filter diameter for a reference vessel diameter from 4.0-5.5 mm. The system is compatible with guide catheters and sheaths with a minimum inner diameter of 0.066″. The embolic filter device itself consists of two parts (Figure 1), a proximal nitinol frame formed out of six alveolar cells and a filter basket made of polytetrafluoroethylene (ePTFE). The proximal frame consists of a nitinol wire forming six diamond-shaped circles that are disposed adjacent to each other to form a ring. This ring is 9 mm long when using the 5 mm-diameter version of the filter and 11 mm long when using the 7 mm-diameter version. It allows an optimized circumferential vessel wall apposition. The filter basket has a hydrophilic heparin coating and is perforated with pores with a nominal pore size of 100 µm. The proximal end of the frame is attached to a 0.014″ PTFE-coated guidewire, and its distal tip passes through the distal end of the filter basket with a shapeable, radiopaque floppy tip. The guidewire rotates freely and is independent of the filter position. The device has four radiopaque markers: three located on the frame and one on the radiopaque collar, which connects the guidewire to the filter. The guidewire is lightly supportive to be able to cross most lesions. In very calcified lesions, it might be advantageous to use an even lighter supportive wire. Therefore, the guidewire is available in a 185 cm-long rapid-exchange configuration and a 300 cm-long over-the-wire configuration. Both the delivery catheter and retrieval catheter have a working length of 150 cm. The delivery catheter has an outer diameter of 3.2 Fr, while the outer diameter of the retrieval catheter is 4.8 Fr and contains a radiopaque marker at its distal tip. The delivery catheter with the guidewire inside is advanced through the lesion. The position is appropriate when the most proximal radiopaque marker of the frame is past the lesion, with adequate room for the tip of the stent delivery system. Next, maintaining the wire position while carefully pulling back the delivery catheter deploys

Table 1. Baseline characteristics.

Characteristic	n = 20
Male gender	12 (60%)
Age (years)	72.2 ± 8.5
Symptomatic status	
Asymptomatic	13 (65%)
Symptomatic	7 (35%)
Recurrent events	4 (20%)
Concomitant disease	
Peripheral arterial occlusive disease	6 (30%)
Prior neck dissection	1 (5%)
Coronary artery disease	10 (50%)
Hypertension	14 (70%)
Diabetes	4 (20%)
Hyperlipidemia	9 (45%)
Smoking	3 (15%)
High-risk criteria	
Anatomical	1 (5%)
Clinical	6 (30%)
Both	1 (5%)
Angiographic baseline characteristics	
Contralateral ICA stenosis	4 (20%)
Percentage stenosis Range	74.2 ± 9.1 55.1-95.3

Data provided as mean ± standard deviation or number (percentage).
ICA = internal carotid artery.

Table 2. Results.

Results	n = 20
Procedure duration	
Procedure time (min)	56.4 ± 15.9
Radiation time (min)	11.9 ± 6.8
Filter time (min)	11.4 ± 6.1
Predilation	2 (10%)
Stent systems	20 (100%)
Protege	11 (55%)
Precise	3 (15%)
Wallstent	4 (20%)
Xact	2 (10%)
Primary endpoint	1 (5%)
Periprocedural	0 (0%)
Until discharge	0 (0%)
At 30-day follow-up	1 (5%)
Secondary endpoint	
Technical success	20 (100%)
Histological analysis	9 (45%)
Structural integrity of the filter	9/9 (100%)
Acute clot material associated with the device	0/9 (0%)
Inflammatory tissue/debris	8/9 (88.9%)

Data provided as mean ± standard deviation or number (percentage).

the filter. The device deployment is completed when the three radiopaque markers on the nitinol frame are separate, indicating the frame is released from the delivery catheter and apposing the vessel wall (Figure 2). Once the filter is positioned, CAS can be performed using any commercially available carotid stent. If excessive debris is collected in the filter and blood flow is obstructed, aspiration of blood proximal to the device is indicated prior to retrieval of the filter. During advancement of the retrieval catheter, the position of the guidewire must be maintained carefully. The retrieval catheter is advanced over the wire to the radiopaque collar under fluoroscopic guidance. Further advancement of the retrieval catheter will lead the frame of the embolic filter to collapse within the catheter. Retrieval of the device is completed when the radiopaque frame markers come together to form a single marker and subsequently overlap with the radiopaque marker on the tip of the retrieval catheter. This means that only the proximal frame of the filter is collapsed within the catheter, while the distal filter bag protrudes out of the catheter. If the decision is made to retrieve the filter completely into the retrieval catheter, this may lead to tearing of the filter bag or rupture and release of embolic debris. Finally, the entire system must be pulled slowly through the guiding catheter under fluoroscopic guidance.

We analyzed our patients for the appearance of any major adverse event (TIA, stroke, myocardial infarction, or death) within 30 days after carotid intervention. *TIA* was defined as an acute neurological deficit lasting <24 hours, with or without evidence of a new ischemic brain infarct upon brain imaging. The criteria for *stroke* were new neurological deficits with new ischemic or hemorrhagic defects detected on computed tomography or magnetic resonance imaging. In addition, we evaluated all procedures in regard to *technical success*, which was achieved when the Gore embolic filter was delivered, placed, and retrieved without causing any acute adverse event.

If patients were not available for clinical 30-day follow-up, they were contacted by telephone. We documented the cardiovascular history and the patient's medication. In cases of new neurological symptoms, a neurological assessment was required and/or office reports were ordered.

The first 9 filters used within this case series were placed in formalin after the interventions and sent to Gore Medical's Products Division in Flagstaff, Arizona for analysis. The filters were tested for structural integrity and the debris captured within the filter bags was histologically analyzed.

Statistical analysis. Statistical analysis was performed on an intention-to-treat principle. Nominal and categorical

variables are displayed as frequencies and percentages. Values for continuous variables are expressed as means ± standard deviation. All data were analyzed using BiAS for Windows (version 10.04).

Results

We included 20 patients in this first single-center experience on the use of the Gore embolic filter in carotid interventions. Mean patient age was 72.2 ± 8.5 years, and 12 patients (60%) were male. Seven patients (35%) had a symptomatic stenosis. Of these, 4 patients had a history of >1 neurological event (including amaurosis fugax, TIA, or ischemic stroke); 1 patient had 2 episodes of TIA at 18 months and 5 months prior to stent implantation. One patient had 2 episodes of amaurosis fugax; the last event was 2 months before the intervention. Two patients suffered both a stroke and an amaurosis fugax within 6 months prior to the procedure. Patient baseline characteristics are outlined in Table 1. Eight patients were considered at high risk for carotid surgery. Anatomical high-risk criteria were present in 2 patients (10%). Both had a history of neck dissection. Seven patients (35%) met clinical high-risk criteria, as they were older than 75 years. Of those, both anatomical and clinical risk factors were present in 1 patient, as he was 77 years old and had a history of neck surgery. On angiography, the mean diameter of stenosis was 74.2 ± 9.1%.

Technical success was achieved in all 20 patients. Mean procedure time was 56.4 ± 15.9 minutes with an average radiation time of 11.9 ± 6.8 minutes. The average filter time from deployment until retrieval of the Gore embolic filter was 12.1 ± 7.1 minutes. In 1 patient, the Gore embolic filter was used as a second embolic protection system. In this particular case, we first decided to use the Gore flow-reversal system (Gore Medical), but after insertion of the balloon sheath into the common carotid artery and placement of the balloon wire in the external carotid artery, test injection of contrast medium showed that even after several placement attempts flow reversal failed and consequently cerebral protection was not established. Therefore, we advanced the embolic filter over the balloon sheath of the flow-reversal device and crossed the target lesion in the ICA.

Predilation before stent placement was performed in 2 patients (10%). The remaining 18 patients underwent direct stent implantation. A stent was implanted in all 20 patients. We chose an open-cell stent design in 14 patients (70%) and a closed-cell stent design in 6 patients (30%). Hybrid stents were not used within this study. The distribution of implanted stent systems is shown in Table 2.

Histological analysis of the filters used in the first 9 patients demonstrated structural integrity of all devices and did not reveal any acute clot material related to the device. Beyond that, debris was detected in 8 out of 9 analyzed filters. The debris was primarily composed of necrotic tissue, mineralization, and intact and degenerated inflammatory nuclei. All aforementioned components were considered common for the degenerative disease process of atherosclerosis and consequently considered to be shed embolic tissue.

Major adverse events (TIA, stroke, myocardial infarction, or death) within 30 days after stent implantation occurred in 1 patient. An 83-year-old woman with an asymptomatic stenosis of the left ICA who was treated with direct stent implantation of a 9 x 30 mm Protégé stent (ev3 Endovascular, Inc) had a TIA with a paresis of the right arm 21 days after the intervention. She was admitted to a local stroke unit. Cerebral computed tomography scan at the time of hospital admission could prove no new ischemic lesion, and the deficits dissolved completely within 24 hours from symptom onset.

In all patients, the Gore embolic filter was used successfully as the cerebral embolic protection device during CAS without the appearance of a neurological complication within the procedure or until discharge.

In 3 procedures, there were minor, non-relevant technical difficulties that did not influence the functionality of the device. In 2 of these cases, friction occurred during deployment of the device; however, this did not result in movement of the wire or the filter in the distal landing zone. Even after removal of the device, no damage or bending of the wire could be detected. In 1 case, the retrieval catheter was caught in the proximal stent struts. Rotating the patient's head to reorient the anatomy and performing a second postdilation thereafter enabled removal of the retrieval catheter.

Discussion

The initial results using the Gore embolic filter show great promise for an effective and safe new embolic protection device in carotid interventions. Within our case series, we saw no relevant technical complications using the device, and no acute periprocedural embolism resulting in neurological disorders occurred. There was only 1 TIA within 30 days of follow-up. No patient suffered a stroke or died. These are the first results in the routine use of the Gore embolic filter as embolic protection system during CAS, and they are favorable when compared with those of the interventional arms of large randomized trials comparing CAS vs CEA. The stroke and death rate after 30 days was 6.8% in the interventional group of the SPACE trial[4] and 9.6% in the EVA-3S study.[5] Even in the CREST trial, in which distal filters were used without exception, 4.4% of the patients randomized to stent implantation had a stroke or died through 30 days of follow-up.[17]

While the Gore embolic filter was specifically designed to avoid the common weaknesses of distal filter devices, one disadvantage remains: crossing of the target lesion by the device is required before cerebral protection can be established.

A possible advantage in design and handling of the system is that rotational freedom between the guidewire and the filter components is enabled. When the device is loaded and deployed, the guidewire is free to rotate independently of

the filter. This allows a more stable placement of the filter in its deployed state in the landing zone, as periprocedural manipulation of the wire is not directly transferred to the filter. In cases with complex anatomy (eg, severe tortuosity), this technical specificity may lead to better wall apposition of the system. The idea of wire movement independent of the filter itself is not unique to the Gore embolic filter; for example, it is implemented in the Emboshield NAV6 (Abbott Vascular) as well. However, this feature alone is not enough to ensure optimal wall apposition; the diamond-shaped frame also helps to ensure a circumferential apposition to the vessel wall. In contrast, the proximal end of the NAV6 is rather round, increasing the risk of inadequate wall apposition in more oval vessels. This results in an increased risk of periprocedural embolization. *In vitro* tests comparing the Gore embolic filter with the NAV6 showed significantly increased filter efficacy with the Gore device ($P<.001$).[20]

Another potential drawback of most distal filter devices is their pore size. Studies using cerebral imaging or periprocedural transcranial Doppler examination demonstrated a higher rate of silent ischemic embolism despite the use of cerebral protection devices.[21-25] This is mainly due to the pore sizes of the filters limiting their protective effect. However, particle sizes smaller than the pore sizes have shown to lead to significant cerebral embolism.[13-15] The Gore Embolic Filter has a distal filter bag pore size of 100 μm, and therefore has the second smallest pore size of all currently commercially available distal protection devices.[26,27] With its three-dimensional fiber network, only the FiberNet device (Medtronic, Inc) generates a smaller pore size of 40 μm.[28] It should be noted, however, that the smaller the pore size of a device, the larger the increase of longitudinal vascular impedance.[29] An *in-vitro* performance assessment comparing five distal filter devices with different pore sizes could not show significantly different volume flow rates between the devices. When filled with debris, an increase in vascular resistance and a decrease in the volume flow rate could be detected for all devices; however, there was no correlation between pore size and changed flow condition.[27] A small pore size is associated with an increased risk of functional closure of the filter by collecting even small particles of debris. This requires permanent periprocedural monitoring by the interventionalist and may necessitate the intermittent aspiration of debris. Therefore, we could see cases with functional filter occlusion due to high filter efficiency when using the Fibernet device (pore size, 40 μm) that required blood aspiration before continuation of the procedure.[28]

Müller-Hülsbeck et al used *in-vitro* benchtop models to prove that the efficacy of debris capture of distal filter devices is highly dependent on the tortuosity of the target vessel.[30-33] They tested four different distal filter devices for filter efficacy as a function of vessel tortuosity. The results showed considerable differences between the tested devices. While the amount of non-captured debris increased non-significantly in severe tortuosity compared with normal anatomy when using the FilterWire EX (Boston Scientific), a significant decrease of filter efficacy ($P<.001$) was detected when using the Angioguard RX (Cordis Endovascular) in tortuous vessels. The Gore embolic filter was designed to allow optimal wall apposition even when positioned in tortuous vessels. Its unique configuration results in a required landing zone, which is only slightly longer than the proximal frame itself. This may be an additional advantage when used in tortuous vessels. *In vitro* tests by Siewiorek et al compared six distal filter devices for embolic protection and found that the Gore embolic filter had the highest capture efficiency of all participating devices with relatively small increase in pressure gradient and vascular impedance after injection of the debris-simulating particles (143 μm, 99.97%; 200 μm,100%).[20]

Study limitations. This report reflects our initial experience with the Gore embolic filter and discussed accordingly only a small sample size. All procedures were performed by a single operator with vast experience in the field of CAS. Therefore, our results may not be completely transferred to other centers. Furthermore, we did not perform routine postprocedure brain diffusion-weighted magnetic resonance imaging/computed tomography in order to detect small and mainly asymptomatic defects caused by the small emboli capable of passing through the pores of the filter.

Conclusion

These initial results of the use of the novel Gore embolic filter satisfy safety and performance criteria for the treatment of carotid artery stenosis. With its specific properties, the system seems to have the potential to compensate at least some of the classic disadvantages of distal filters for embolic protection. Further investigation and evaluation are justified and needed.

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From [1]CardioVascular Center Frankfurt CVC, Frankfurt, Germany; and [2]Anglia Ruskin University, Chelmsford, United Kingdom.

Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. All authors report grant support from Abbott Vascular, grants and non-financial support from Access Closure, Angiomed, Arstasis, Atritech, Atrium, Avinger, Bard, Boston Scientific, Bridgepoint, Cardiac Dimensions, CardioKinetix, CardioMEMS, Coherex, Contego, CSI, EndoCross, EndoTex, Epitek, Evalve, eve, FlowCardia, Gore, Guidant, Guided Delivery Systems, Inc, InSeal Medical, Lumen Biomedical, Kyoto Medical, Lifetech, Lutonix, Medinol, Medtronic, NMT, Occlutech, Osprey, Ovalis, Pathway, PendraCare, Percardia, pfm Medical, Sadra, St. Jude Medical, Sorin, Spectranetics, SquareOne, Trireme, Trivascular, Velocimed, and Veryan; other support from Access Closure, CardioKinetix, Lumen Biomedical, and Velocimed.

Manuscript submitted March 1, 2016, provisional acceptance given April 13, 2016, final version accepted May 2, 2016.

Address for correspondence: Prof Dr med Horst Sievert, CardioVascular Center Frankfurt, Seckbacher Landstrasse 65, 60389 Frankfurt, Germany. Email: info@cvcfrankfurt.de